FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Menu Labeling Campaign Focus Groups (Formative Research and Stimuli Testing)

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**
   The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Analytics and Outreach is seeking OMB approval under the generic clearance 0910-0497 for the focus group project, "Menu Labeling Campaign Focus Groups (Formative Research and Stimuli Testing)." This is the second phase of this study, the first phase of which was approved on April 21, 2016, and completed in July 2016. The purpose of this focus group study is to collect qualitative information to help develop educational messages about FDA's menu labeling requirements. The study will explore (1) participants' experiences related to making healthful food choices at restaurants (2) participants' attitudes and motivations related to calorie declarations, when available, on restaurant menus and (3) participants' views about how best to support consumers in using calorie information in making food selections for their children and themselves when dining out.

   The research will help us to explore: 1) participants' perceptions of what constitutes "healthy" eating when choosing food for their children; 2) participants' perceptions of calorie information listed on restaurant menus and their use of the information in making food selections when dining out; 3) participants' media habits related to obtaining information about healthy eating; 4) characteristics of past health information or advertising campaigns that have affected participants' decision making; and 5) participants' reactions to draft campaign concepts about calorie labeling on restaurant menus and making healthful food choices when dining out.

   FDA plans to use the study to inform development of consumer education and outreach materials about menu labeling prior to the compliance date of the regulations.

2. **Intended use of information:**
   This information collection request involves qualitative research that will be used to inform development of consumer messages about using the calorie information listed on menus as a tool for making food selections and managing calorie consumption when dining out.

3. **Description of respondents:**
   A total of 8 focus groups are planned. All groups will include women who have one or more children between the ages of 3 and 10 years. The study will enroll participants who frequent fast-food chain restaurants at least once a week and who have purchased a lunch

or dinner meal for their children at such restaurants at least once in the week prior to screening. The groups will include women living in households with a size-adjusted income that is approximately two-thirds of to double the U.S. median household income, ranging from $41,869 to $125,608 in 2014[1]. Some groups will be segmented by race/ethnicity depending on the demographic makeup of the selected location; for example, we will aim to recruit a group of 8 to 10 African American participants in both Maryland and in Ohio, and a group of 8 to 10 Hispanic American participants in California and Texas. No more than 10 participants will participate in a group (see Appendix I, Participant Screener). FDA has contracted with RTI International to conduct these in-person focus groups.

4. **Date(s) to be conducted and location(s):**

Focus groups will be conducted approximately one month from the date of OMB approval. The focus groups will be conducted in four states: California, Maryland, Ohio, and Texas. These locations were chosen to represent consumers from a range of geographic locations populated with fast food restaurants. The selected locations offer suitable focus group facilities and recruitment capabilities that will enable us to recruit groups of ethnically diverse, middle-income participants who meet the criteria described in section 3 above.

FDA plans to complete these focus groups by December 2016.

5. **How the Information is being collected:**

Recruitment Information

Staff from the focus group facilities will use their in-house databases to recruit participants via telephone using the participant screener (Appendix I). The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. Facilities will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. The facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Focus Group Discussions

RTI staff members will serve as moderators for all focus groups. FDA staff members will observe most, if not all, of the sessions from the observation rooms at the focus group facilities or remotely using streaming technology.

The moderator will use the attached moderator guide (Appendix II) to ensure that all relevant topic areas and messages (Appendix III) are addressed. The focus group facilities will make audio and video recordings to ensure a verbatim record of the proceedings is captured.

The Contractor will comply with safeguards for ensuring participant information is kept private to the extent permitted by law. The last names of the participants will not appear on any focus group materials. Verbatim quotes included in the final report will not be attributed to any individual.

[1] See http://www.pewresearch.org/fact-tank/2015/12/09/are-you-in-the-american-middle-class/

6. **Number of focus groups:**
   A total of 8 focus groups are planned. FDA plans to complete the focus groups by December 2016 so that we can use the study findings to inform agency education efforts related to menu labeling that may be needed when the regulations go into effect.

7. **Amount and justification for any proposed incentive:**
   RTI periodically consults with facilities that routinely host focus groups to determine incentive rates. Based on these consultations, RTI proposes an incentive of $75 for 90 minutes to ensure that we are able to attract a reasonable cross section of participants who earn household incomes within our preferred range.

   Our experience in conducting focus group research indicates that offering nonmonetary incentives or an incentive that is below the accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following:

   - Increased time and cost of recruitment
   - Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants)
   - Increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers recruited by the scheduled date of the focus group, which not only incurs additional costs, but also puts additional burden on the recruited participants who have to reschedule their participation in the focus group.

   Our proposed incentive amount will help ensure that respondents honor their commitment of participating in the focus group focus groups. Our incentive was chosen based on 1) an estimated cost related to childcare for 3 hours (e.g., approximate travel time to and from facility, time to park a vehicle, check-in and check-out procedures, and the 90-minute focus group discussion), which is approximately $48[2]; 2) an estimated cost for an average driving commute to and from the facility of approximately $18[3]; and 3) our contractor's and other researchers' experiences with using nonmonetary incentives, which generally produce participation rates no better than the complete absence of any incentives.[4] The proposed amount of $75 is comparable to what has been the level of reimbursement for the target audiences in similar government funded activities. Mothers of young children are often more difficult to recruit than more general audiences and the incentive needs to be enough to help the participants cover outside childcare costs if needed. As noted above, we expect that lower or nonmonetary incentives will necessitate

[2] Assumes an hourly rate of $16 per hour for a professional babysitter
[3] Assumes travel by automobile; calculation derived from average annual commuting costs reported at https://www.census.gov/hhes/commuting/files/JSM_Proceedings_paper.pdf
[4] See: Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly,* 57, 62-79; Dykema, J. et al. (2012). Use of monetary and nonmonetary incentives to increase response rates among African Americans in the Wisconsin pregnancy risk assessment monitoring system. *Maternal and child health journal*, *16*(4), 785-791; Singer, E., & Kulka, R. A. (2002). Paying respondents for survey participation. In: *Studies of welfare populations: Data collection and research issues*, 105-128.

over-recruitment by higher percentages and result in longer recruiting time as well as higher overall project costs.

The importance of monetary compensation for focus group participation has been discussed by Krueger and Casey (2014), who indicate that offering minimal levels of monetary compensation can help ensure that sufficient numbers of participants will attend, thereby yielding more useful research results.[5] Further, in a meta-analysis of 38 experiments and quasi-experiments, Church (1993) found that providing cash incentives for participation was far more effective than nonmonetary gifts in generating survey response, and prepaid monetary incentives yielded an average increase of 19.1 percentage points over comparison groups.[6] Finally, the importance of monetary incentives has been corroborated in experiences related to the National Adult Literacy Survey by Berlin and colleagues (1992)[7] and internal proprietary research conducted by our contractor, RTI.

8. **Questions of a Sensitive Nature:**
   None.

9. **Description of statistical methods (i.e., sample size & method of selection):**
   The Contractor will contact prospective participants by telephone and screen them for eligibility to participate (Appendix I). The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. Facilities will conduct recruitment and ensure that the needed number of participants show up for their scheduled time slot. This study employs qualitative methods and does not entail the use of any statistical methods.

   Table 1 shows the estimated annual reporting burden for the groups, assuming 10 participants per group.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Table 1.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	480	5	40
Focus group discussion	80	90	120
Total			160

[5] Krueger, R.A. & M.A. Casey. (2014). Focus groups: A practical guide for applied research. (5th ed.). Thousand Oaks, CA: Sage Publications, Inc.
[6] Church, A.H. (1993). Estimating the effect of incentives on mail survey response rates: A meta-analysis. *Public Opinion Quarterly,* 57, 62-79.
[7] Berlin, M., L. Mohadjer, J. Waksberg, A. Kolstad, I. Kirsch, D. Rock, & K. Yamamoto. An experiment in monetary incentives. American Statistical Association, Proceedings of Survey Research Methods Section; Alexandria, VA: 1992. pp. 393–398.

REQUESTED APPROVAL DATE: September 26, 2016

NAME OF PRA ANALYST & PROGRAM CONTACT:
Ila S. Mizrachi (PRA Analyst)
Ila.Mizrachi@fda.hhs.gov
301-796-7726

Kathleen Yu (Program Contact)
Kathleen.Yu@fda.hhs.gov
240-402-2891

FDA CENTER: Center for Food Safety and Applied Nutrition